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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/893,535
Filing Date: June 29, 2001
Appellant(s): ARBOGAST ET AL.

MAILED

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GROUP 3600

Eric M. Gayan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/18/2007 appealing from the Office action mailed 08/08/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,463,351	CLYNCH	10-2002
6,581,204 B1	DeBUSK	6-2003

2002/0099631 A1	VANKER	7-2002
2001/0051787 A1	HALLER	12-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-37, 39, 46-48, 65-67 and 82 are rejected under 35 U.S.C. 102(e) as being unpatentable by Clynch (U.S. Patent No. 6,463,351 B1).

As per claim 31, Clynch discloses a method of configuring a medical device, comprising the steps of:

i. populating a digital repository with information corresponding to a plurality of medical device components (Clynch; col.4, lines 49-53 and col.7, line 61 to col.18, line10);

ii. interviewing a patient having a need for a medical device to determine at lest one patient attribute (Clynch; col.5, lines 1-6);

iii. storing the at least one patient attribute in a memory (Clynch; col.6, lines 36-40 and col. 9, lines 7-12); and

iv. querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65 and col. 4, lines 14-39).

As per claim 32, Clynch discloses the method of claim 31, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 33, Clynch discloses the method of claim 31, further comprising the step of: customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient (Clynch; col.7, lines 28-44).

As per claim 34, Clynch discloses the method of claim 31, wherein the querying step comprises:

i. querying the digital repository for a plurality of subsets of medical device components based on the at least one patient attribute, the subset of medical device components corresponding to a medical device meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65); and

ii. ranking the plurality of subsets based on a ranking criteria (Clynch; col.7, lines 28-34).

As per claim 35, Clynch discloses the method of claim 34, wherein the ranking criteria is at least one of a weight of the medical device, a height of the medical device, a width of the medical device, a cost of the medical device, an activity level supported by the medical device, and an inventory status of the medical device (Clynch; col.7, lines 34-44).

As per claim 36, Clynch discloses the method of claim 34, further comprising the step of:

i. selecting one of the plurality of subsets (Clynch; col.7, lines 63-65);

ii. customizing the one of the plurality of subsets to create a customized medical device further meeting the need of the patient (Clynch; col.7, line 65 to col.8, line 10); and

iii. ordering the customized medical device (Clynch; col.3, lines 19-24).

As per claim 37, Clynch discloses the method of claim 36, wherein the ordering step comprises reviewing the customized medical device prior to ordering (Clynch; col.3, lines 12-14).

As per claim 39, Clynch discloses the method of claim 31, wherein the interviewing step comprises entering the at least one patient attribute via at least one of a personal data assistant, a digitizer, a digital camera, and a digital video camera (Clynch; col.6, lines 50-54 and col.9, lines 7-12).

As per claim 46, Clynch discloses a system for configuring a medical device, comprising:

i. means for populating a digital repository with information corresponding to a plurality of individual medical device components (Clynch; col.4, lines 49-53 and col.7, lines 61-63 and col. 4, lines 14-39);

ii. means for interviewing a patient having a need for a medical device to determine at least one patient attribute (Clynch; col.5, lines 1-6);

iii. means for storing the at least one patient attribute in a memory (Clynch; col.6, lines 36-40 and 50-54); and

iv. means for querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65 and col. 4, lines 14-39).

As per claim 47, Clynch discloses the system of claim 46, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 48, Clynch discloses the system of claim 46, further comprising: means for customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient (Clynch; col.7, lines 28-44).

As per claim 65, Clynch discloses a method for configuring a medical device, comprising the steps of:

i. populating a digital repository with information corresponding to a plurality of individual medical device components (Clynch; col.4, lines 49-53 and co1.7, lines 61-63 and col. 4, lines 14-39);

ii. populating the digital repository with patient historical information associated with a patient (Clynch; col.9, lines 7-12);

iii. interviewing the patient having a need for a medical device to determine at least one patient attribute (Clynch; col.5, lines 1-6);

iv. storing the at least one patient attribute in a memory via a digital communication link (Clynch; col.6, lines 36-43);

v. querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient (Clynch; co1.7, lines 22-44 and 61-65 and col. 4, lines 14-39);

vi. ordering the medical device over the digital communication link (Clynch; col.3, lines 12-14); and

vii. storing information corresponding to the medical device in the digital repository associated with the patient (Clynch; col.6, lines 36-40 and col. 9, lines 7-12).

As per claim 66, Clynch discloses the method of claim 65, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 67, Clynch discloses the method of claim 65, wherein the patient historical information comprises at least one of reimbursement information and L code information (Clynch; col.9, lines 7-12).

> Examiner considers that this information includes L-code information for patients; which is described in applicant's specification as generating letters of necessity for patients, and for querying the practitioner local database or the central database for patient-specific information.

As per claim 82, Clynch discloses the method of claim 31, further comprising the steps of:

> i. customizing at least one of the subset of medical device components to create a customized medical device further meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65);
>
> ii. storing a customization result of the customizing step in the digital repository (Clynch; col.7, lines 22-44 and 61-65);
>
> iii. comparing the customization result to the subset of medical device components to identify a customization trend (Clynch; col.7, lines 28-44 and 61-63); and

iv. adjusting an algorithm used in the querying step based on the customization trend causing a different subset of medical device components to be queried based on the at least one patient attribute (Clynch; col.7, lines 28-44 and 61-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of DeBusk et al. (U.S. Patent No. 6,581,204 B1).

As per claim 1, Clynch discloses a system for configuring a medical device, comprising:

i. a digital repository populated with entries defining a plurality of medical device components, each entry associated with an individual medical device component and having at least one patient attribute indicator (Clynch; col. 4, lines 49-53 and col. 7, line 61 to col. 8, line 10);

ii. a processor (Clynch; col.3 ,lines 12-19); and

iii. a computer readable medium encoded with processor readable instructions that when executed by the processor implement (Clynch; col.3, lines 39-53)

iv. a practitioner user interface mechanism configured to provide a practitioner with access to entries in the digital repository via a network and to allow the practitioner to provide at least one patient interview answer indicator (Clynch; col.5 ,lines 1-6 and col. 6, lines 40-43),

v. a patient interview mechanism configured to receive over the network the at least one patient interview answer indicator corresponding to an attribute of a patient and to store the at least one patient interview answer indicator in a memory (Clynch; col.5 ,lines 1-6), and a

vi. configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient (Clynch; col.7 ,lines 22-44 and 61-65).

Clynch fails to expressly teach the individual medical device having component identification indicator and component class indicator, per se, since it appears that Clynch is more directed to storing default modifications in the database and when the modification is selected, the shape and location of the modification is displayed on the image and updated on the pull down modification menu. However, this feature is well known in the art, as evidenced by DeBusk et al.

In particular, DeBusk et al. discloses a modular tracking and profiling system wherein individual medical device component having component identification indicator (DeBusk et al, item 114) and component class indicator (DeBusk et al, item 112)(see DeBusk et al; col.17, line 56 to col.18, line 17).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the storing default modifications in the database and when the modification is selected, the shape and location of the modification is displayed on the image and updated on the pull down modification menu with the individual medical device having component identification indicator and component class indicator with the motivation of minimizing inventory and labor costs (DeBusk et al; col. 17, lines 26-34).

As per claim 2, Clynch discloses the system of claim 1, wherein the medical device comprises at least one of a lower extremity prosthetic device, an upper extremity prosthetic device, a lower extremity orthotic device, an upper extremity orthotic device, and a spinal orthotic device (Clynch; col.5, lines 4-6).

As per claim 3, Clynch discloses the system of claim 1, wherein:

i. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-43)

ii. a customization mechanism configured to at least one of add, remove, and modify at least one entry of the subset of entries selected by the configurator mechanism, and the practitioner user interface mechanism is further configured to provide access to the customization mechanism (Clynch; col.7, lines 22-44 and 61-65).

As per claim 4, Clynch discloses the system of claim 3, wherein the practitioner user interface mechanism is further configured to provide a summary page of components customized by the customization mechanism (Clynch; col.6, lines 5-15).

As per claim 5, Clynch discloses the system of claim 1, wherein:

i. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-43)

ii. a medical device shopping mechanism configured to place an order for the medical device and to store order information in the digital repository, and the practitioner user interface mechanism is further configured to provide access to the medical device shopping mechanism (Clynch; col.5, line 53 to col. 6, line 17).

As per claim 8, Clynch discloses the system of claim 1, wherein at least a portion of the network comprises an Internet protocol based network (Clynch; col.37, lines 48-53).

As per claim 9, Clynch discloses the system of claim 1, wherein a least a portion of the network is the Internet (Clynch; col.37, lines 48-53).

As per claim 10, Clynch discloses the system of claim 1, wherein the digital repository comprises:

i. a central digital repository (Clynch; col.7, lines 61-63 and col. 1, line 66 to col. 2, line 28), and

ii. a practitioner local digital repository remote from the central database (Clynch; col.3, lines 12-24 and Fig. 2).

As per claim 11, Clynch discloses the system of claim 10, wherein: at least one of the practitioner local digital repository and the central digital repository is further populated with patient historical entries, the patient historical entries each associated with an individual patient and having a patient identification indicator, and at least one patient history indicator (Clynch; col.9, lines 7-12).

Examiner considers that since the patient has access to the local physician's office, the patient should have an identification indicator and history indicator.

As per claim 12, Clynch discloses the system of claim 11, wherein the at least one patient history indicator comprises information corresponding to a medical device of the individual patient (Clynch; col.9, lines 7-12 and col. 5, lines 1-4).

As per claim 13, Clynch discloses the system of claim 12, and

The obviousness of modifying the teaching of Clynch to include the medical device of an individual patient comprises an identification number (as taught by DeBusk et al) is as addressed above in the rejection of claim 1 and incorporated herein (DeBusk et al; col. 17, lines 26-34).

As per claim 14, Clynch discloses the system of claim 11, wherein: the patient historical entries further have at least one patient care indicator (Clynch; col.9, lines 7-12 and col. 5, lines 1-4).

As per claim 16, Clynch discloses the system of claim 15, wherein the reimbursement information comprises an L code indicator (Clynch; col.9, lines 7-12).

Examiner considers that this information includes L-code information for patients; which is described in applicant's specification as generating letters of necessity for patients, and for querying the practitioner local database or the central database for patient-specific information.

As per claim 19, Clynch discloses the system of claim 1, wherein:

i. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 12-19)

ii. a patient letter of necessity generation mechanism configured to generate a letter of necessity for the patient based on information stored in the digital repository and to store the letter of necessity in the digital repository (Clynch; col.6, lines 5-15), and

iii. the practitioner user interface mechanism is further configured to provide access to the patient letter of necessity generation mechanism (Clynch; col.9, lines 7-12).

As per claim 20, Clynch discloses the system of claim 1, wherein the digital repository comprises a database (Clynch; col.7, lines 61-63).

As per claim 22, Clynch discloses the system of claim 21, wherein the external device is at least one of a digitizer, a digital camera, and a digital video camera (Clynch; col.6, lines 50-54 and col.9, lines 7-12).

As per claim 23, Clynch discloses the system of claim 1, wherein:

i. the entries in the digital repository further have a ranking indicator (Clynch; col.7, lines 28-34), and

ii. the configurator mechanism is further configured to select a plurality of subsets of entries from the digital repository based on the at least one patient interview answer indicator in the memory, each of the plurality of subsets including entries corresponding to individual medical device components of a medical device meeting the need of the patient and being ranked based on the ranking indicator of the entries (Clynch; col.7, lines 22-44 and 61-65).

As per claim 24, Clynch discloses the system of claim 23, wherein the ranking indicator comprises at least one of a component cost indicator, a component weight indicator, a component height indicator, a component width indicator, a component activity level indicator, and an inventory indicator (Clynch; col.7, lines 34-44).

As per claim 25, Clynch discloses the system of claim 23, wherein:

i. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-53)

ii. a customization mechanism configured to select one of the plurality of subsets of entries and at least one of add, remove, and modify at least one entry of the one of the plurality of subsets of entries selected by the configurator mechanism (Clynch; col.5, lines 53-67), and

iii. the practitioner user interface mechanism is further configured to provide access to the customization mechanism (Clynch; col.5, lines 53-67).

As per claim 26, Clynch discloses the system of claim 25, wherein:

i. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-53)

ii. a medical device shopping mechanism configured to place an order for the medical device corresponding to the one of the plurality of subsets of entries selected by the customization mechanism and to store order information in the digital repository, and the practitioner user interface mechanism is further configured to provide access to the medical device shopping mechanism (Clynch; col.5, line 53 tocol.6, line 17).

As per claim 27, Clynch discloses the system of claim 25, wherein the practitioner user interface mechanism is further configured to provide a summary page of components customized by the customization mechanism (Clynch; col.6, lines 5-15).

As per claim 28, Clynch discloses the system of claim 1, wherein:

i. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-43)

ii. a catalog mechanism configured to select a subset of entries from the digital repository based on a query and to provide the subset of entries to the practitioner user interface mechanism (Clynch; col.7, lines 22-44 and 61-65), and

iii. a medical device component shopping mechanism is configured to place an order for a medical device component corresponding to at least one selected entry of the subset of entries and to store order information in the digital repository (Clynch; col.5, line 53 to col. 6, line 17)

iv. the practitioner user interface mechanism is further configured to accept the query from a user, to provide the query to the catalog mechanism, and to select the at least one selected entry of the subset of entries provided by the catalog mechanism (Clynch; col.5, line 53 to col. 6, line 17).

As per claim 29, Clynch discloses the system of claim 28, wherein:

i. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implement (Clynch; col.3, lines 39-43)

ii. a customization mechanism configured to select at least one of the subsets of entries and at least one of add, remove, and modify at least

one entry of the one of the plurality of subsets of entries selected by the catalog mechanism, and the practitioner user interface mechanism is further configured to provide access to the customization mechanism (Clynch; col.5, line 53 to col. 6, line 17).

As per claim 30, Clynch discloses the system of claim 29, wherein the practitioner user interface mechanism is further configured to provide a summary page of components customized by the customization mechanism (Clynch; col.6, lines 5-15).

As per claim 80, Clynch discloses the system of claim 3, wherein:

i. the customization mechanism is further configured to store a customization result in the digital repository indicating a change made to the subset of entries selected by the configurator mechanism (Clynch; col.7, lines 22-44 and lines 61-65)., and

ii. the computer readable medium is further encoded with processor readable instructions that when executed by the processor further implements (Clynch; col.3, lines 39-43).

iii. an algorithm adjustment mechanism configured to adjust an algorithm of the configurator mechanism based on the customization result stored in the digital repository, the adjustment causing the configurator mechanism to select a different subset of entries based on the at least one patient interview answer indicator (Clynch; col.7, lines 28-44).

As per claim 81, Clynch discloses the system of claim 80, wherein the algorithm adjustment mechanism comprises an application of artificial intelligence (Clynch; col.7, lines 28-44).

Claims 38, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of Vanker et al. (U.S. Patent Publication No. 2002/0099631 A1).

As per claim 38, Clynch discloses the method of claim 36.

Clynch fails to expressly teach the determining all applicable price discounts for the medical device for the practitioner, per se, since it appears that Clynch is more directed to provide a method for producing medical devices such as prosthetic, orthotic and precision fit devices. However, this feature is well known in the art, as evidenced by Vanker et al.

In particular, Vanker et al. discloses determining all applicable price discounts for the medical device for the practitioner (Vanker et al., paragraph 0025).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the method for producing medical devices such as prosthetic, orthotic and precision fit devices with determining all applicable price discounts for the medical device for the practitioner with the motivation of having a detailed usage and sale records component enables the

buyers to use a communications interface (Vanker et al., paragraph 0136).

As per claim 49, Clynch discloses the method of claim 46.

The obviousness of modifying the teaching of Clynch to include determining all applicable price discounts for the medical device for the practitioner (as taught by Vanker et al) is as addressed above in the rejection of claim 38 and incorporated herein (Vanker et al., paragraph 0136).

Claims 68, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of Haller et al. (U.S. Patent Publication No. 2001/0051787 A1).

As per claim 68, Clynch discloses the method of claim 65.

Clynch fails to expressly teach sharing information in the digital repository with an external system, per se, since it appears that Clynch is more directed to provide a method for producing medical devices such as prosthetic, orthotic and precision fit devices which most of the modification of the digital image can be accomplished in a local physician's office that the patient has already access. However, this feature is well known in the art, as evidenced by Haller et al.

In particular, Haller et al. discloses sharing information in the digital repository with an external system (Haller et al., paragraph 0177).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the method for producing medical devices such as prosthetic, orthotic and precision fit devices which most of the modification of the digital image can be accomplished in a local physician's office that the patient has already access with sharing information in the digital repository with an external system with the motivation of patient, health care provider or insurer confirm acceptance of charges for updates or changes before or at the same time as they are implemented (Haller et al.; paragraph 0177).

As per claim 69, Clynch discloses the method of claim 68.

Clynch fails to expressly teach the external system comprises at least one of a patient management system, a billing system, and an insurance reimbursement system, per se, since it appears that Clynch is more directed to provide a method for producing medical devices such as prosthetic, orthotic and precision fit devices which most of the modification of the digital image can be accomplished in a local physician's office that the patient has already access. However, this feature is well known in the art, as evidenced by Haller et al.

In particular, Haller et al. discloses the external system comprises at least one of a patient management system, a billing system, and

an insurance reimbursement system (Haller et al., paragraph 0177).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the method for producing medical devices such as prosthetic, orthotic and precision fit devices which most of the modification of the digital image can be accomplished in a local physician's office that the patient has already access with the external system comprises at least one of a patient management system, a billing system, and an insurance reimbursement system with the motivation of patient, health care provider or insurer confirm acceptance of charges for updates or changes before or at the same time as they are implemented (Haller et al.; paragraph 0177).

Claims 6, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) and DeBusk et al. (U.S. Patent No. 6,581,204 B1) as described above for rejection of claim 1, in further view of Vanker et al. (U.S. Patent Publication No. 2002/0099631 A1).

As per claim 6, Clynch discloses the method of claim 5.

The obviousness of modifying the teaching of Clynch to include determining all applicable price discounts for the medical device for the practitioner (as taught by Vanker et al) is as addressed above in the

rejection of claim 38 and incorporated herein (Vanker et al., paragraph 0136).

As per claim 7, Clynch discloses the method of claim 1.

Clynch fails to expressly teach at least a portion of the practitioner user interface mechanism is accessible via a personal data assistant, per se, since it appears that Clynch is more directed to any personal computer system commonly available in most physician's clinics (Clynch; col. 7, lines 17-22). However, this feature is well known in the art, as evidenced by Vanker et al.

In particular, Vanker et al. discloses practitioner user interface mechanism is accessible via a personal data assistant (Vanker et al., paragraph 0042).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the method for producing medical devices such as prosthetic, orthotic and precision fit devices which most of the modification of the digital image can be accomplished in a local physician's office that the patient has already access with the practitioner user interface mechanism is accessible via a personal data assistant with the motivation of communication with the central independent repository without need for a specific and proprietary communications protocol (Vanker et al.; paragraph 0042).

Claims 15, 17, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) and DeBusk et al. (U.S. Patent No. 6,581,204 B1) as described above for rejection of claim 1, in further view of Hailer et al. (U.S. Patent Publication No. 200210099631 A1).

As per claim 15, Clynch discloses the system of claim 14.

Clynch fails to expressly teach the patient care indicator comprises reimbursement information, per se, since it appears that Clynch is more directed to provide a method for producing medical devices such as prosthetic, orthotic and precision fit devices which most of the modification of the digital image can be accomplished in a local physician's office that the patient has already access. However, this feature is well known in the art, as evidenced by Haller et al.

In particular, Haller et al. discloses the patient care indicator comprises reimbursement information. (Haller et al., paragraph 0177).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the method for producing medical devices such as prosthetic, orthotic and precision fit devices which most of the modification of the digital image can be accomplished in a local physician's office that the patient has already access with patient care indicator comprises reimbursement information with the motivation of patient, health

care provider or insurer confirm acceptance of charges for updates or changes before or at the same time as they are implemented (Haller et al.; paragraph 0177).

As per claim 17, Clynch discloses the system of claim 11.

The obviousness of modifying the teaching of Clynch to include interface with an external system (as taught by Haller et al) is as addressed above in the rejection of claim 68 and incorporated herein (Haller et al., paragraph 0177).

As per claim 18, Clynch discloses the system of claim 17.

The obviousness of modifying the teaching of Clynch to include the external system comprises at least one of a patient management system, a billing system, and an insurance reimbursement system (as taught by Haller et al) is as addressed above in the rejection of claim 69 and incorporated herein (Haller et al., paragraph 0177).

As per claim 21, Clynch discloses the system of claim 1.

The obviousness of modifying the teaching of Clynch to include interface with an external system (as taught by Haller et al) is as addressed above in the rejection of claim 68 and incorporated herein (Haller et al., paragraph 0177).

(10) Response to Arguments

In the Appeal Brief filed 06/18/2007, Appellant makes the following arguments:

A. Clynch does not teach interviewing a patient.

B. Clynch does not teach querying a digital repository of medical device components.

Examiner will address Appellant's arguments in sequence as they appear in the brief.

Argument A:

In response to Appellant's first argument, the Examiner respectfully submits that the method claim 31 recites: "interviewing a patient having a need for a medical device to determine at least one patient attribute"; Clynch teaches "a method of producing a medical device, such as a prosthetic or orthotic structure" in abstract, "In accordance with the method, the process of constructing a medical device begins in a physician's clinic 10 where in step 20, a modeling material is fitted to the body part of a patient requiring a medical device. As described above, the medical device may be a prosthetic, orthotic, radiological or any other anthropometric precision fit device" in col. 5, lines 1-6. It is well known to one of the ordinary skill in the art, at the time of the invention, that there has to be an interaction between the patient and the physician, and physician would obtain at least one patient attribute (such as patient's weight, height, size and shape of the desired prosthetic medical device, or patient's activity level).

Argument B:

In response to Appellant's second argument, the Examiner respectfully submits that Clynch teaches "The digitized scanned image 60 of the model is displayed in a window on the left hand side of the monitor. The modeled image shown is that

of a below knee amputation, but any body portion may be imaged, including a foot, knee, leg, hip, back, shoulder, torso, arm, hand, neck or head for example. A pull down menu 62 is displayed in a window adjacent the scanned image. The pull down menu 62 includes the default options for modifying the scanned image to produce a mold to be used in the manufacture of the medical device or to produce a medical device directly from the modified image. The list of default modifications is available on a scrolling sub-menu 64. The options on the scrolling sub-menu depend on the type of medical device to be produced. Regardless of the type of device, a "uniform shrink" and a "smooth" option are available to permit the image to be uniformly shrunk in order to compensate for the thickness of the model and yield an accurately dimensioned image representative of the body part for which the device is to be produced. The smooth option converts the surface of the modified image into a smooth surface having the appearance of the mold that will be produced from the machine code generated from the modified image. Other options on the modification menu, as noted above, are device dependent. For example, the options available for a below knee prosthetic device include modifications for: Patellar Tenon Bar, Crest of Tibia, Supracondylar Constriction, Anterior Prominence of Femoral Condyle, Anterior Latter Tibial Prominence, Head of the Fibula Lateral Femoral Condyle, Distal End of the Fibula, Adductot Tubercal, Distal End Extension, and Posterior Wall Extension." in col. 7, lines 24-52 and in figure 3. Examiner respectfully submits that these options of body parts may form a whole leg, therefore they

may be components of a complex medical device. Clynch continues in col. 7, lines 53-65 that "The default modification set for a knee orthosis includes Crest of Tibia, Anterior Lateral Tibial Prominence, Supracondylar Constriction, Medial Anatomical Joint and Lateral Anatomical Joint. The default modification set for a podiatric orthosis include modifications directed to correcting/relieving the effects of plantar fasiitis or calcaneous heel spur, Metatarsalgia or Morton's Neuroma, sesamoiditis and pescavus. Each of these default modifications are stored in a database of imperically derived data based on prior successful medical devices. When a default modification is selected, the shape and location of the modification is displayed on the image and updated on the pull down modification menu 62." And in col. 3, lines 12-24, Clynch teaches "the digital image to be manipulated and modified with the assistance of a database of default modifications", therefore Clynch teaches querying a digital repository (or database) of medical device components.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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DBC

September 12, 2007

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